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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE, INC., a Delaware)	
corporation,)	
)	
)	C.A. No. 05-590 GMS
Plaintiff,)	
)	CONFIDENTIAL
v.)	FILED UNDER SEAL
)	
DEXCOM, INC., a Delaware corporation,)	
)	
)	
Defendant.)	
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DEXCOM, INC.'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO STAY
PENDING RE-EXAMINATION OF THE PATENTS IN SUIT

Josy W. Ingersoll (No. 1088)
John W. Shaw (No. 3362)
Young Conaway Stargatt & Taylor
1000 West Street
Brandywine Building, 17th Floor
Wilmington, DE 19801
Telephone: (302) 571-6689
jingersoll@ycst.com

Attorneys for Defendant
DEXCOM, INC.

Of Counsel:

MORRISON & FOERSTER LLP
David C. Doyle
M. Andrew Woodmansee
Brian M. Kramer
3811 Valley Centre Drive, Suite 500
San Diego, CA 92130-2332
(858) 720-5100

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INTRODUCTION

Abbott's entire argument in its Answering Brief boils down to this: Abbott is *entitled* to an injunction against DexCom and entering a stay would deny Abbott its theoretical right to seek that injunction. Abbott speaks in terms of entitlement but references only hypothetical harm that could occur if DexCom's "infringing" product enters the market. Oblivious to the fact that "a preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted,"¹ Abbott asks this Court to assume infringement and ignore the "substantial new questions of patentability" recognized by the PTO in already granting two of the four pending reexamination requests.² Abbott cites no authority for the proposition that a court *cannot* stay litigation once the patent holder has announced its intention to seek an injunction. No such case exists. After all, every granted stay motion thwarts a patent holders' theoretical right to seek a preliminary injunction. If Abbott's sweeping proposition were the law, no court would have ever stayed a case due to pending reexamination proceedings.

Abbott offers only speculation in its Answering Brief, arguing that its hypothetical market share for its own yet-to-be-approved glucose monitor could hypothetically erode during the pendency of the reexamination. Abbott acknowledges that its own product is approximately ten months from receiving FDA approval (which, of course, is not guaranteed). Undaunted by the speculative nature of its theoretical "irreparable harm," Abbott would have this Court deny the motion to stay, enjoin

¹ *Intel Corp. v. ULSI System Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993) (reversing injunction).

² At the time DexCom filed its Motion To Stay, the PTO had not yet granted any of the Reexamination Requests. Since DexCom filed its Opening Brief on February 22, 2006, the PTO has ordered reexamination of U.S. Patent No. 6,329,161 ("the '161 Patent") on February 28, 2006, and U.S. Patent No. 6,284,478 ("the '478 Patent") on February 24, 2006. Copies of the PTO's orders granting reexamination are attached as Exs. A and B to this Reply.

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DexCom's future launch of an important medical device, and allow the parties to spend millions of dollars—and countless hours of this Court's time—litigating patent claims that have a 74% chance of being canceled or changed. Abbott cannot overcome the liberal policy in favor of granting stays pending reexamination, and case law explicitly rejects potential loss of market share as a form of prejudice that can preclude a stay pending patent reexamination.

Abbott's argument—that entry of a stay will thwart its future efforts to obtain an injunction—highlights the prematurity of its entire case against DexCom. Simply put, there is nothing for the Court to enjoin. DexCom has no product on the market. The FDA has not even approved DexCom's application to market and sell its short-term continuous glucose monitoring device. Abbott has not filed its motion for preliminary injunction because even Abbott recognizes that it would be premature to do so. Abbott attempts to obscure the prematurity of this lawsuit by quoting statements from DexCom's counsel during the February 23, 2006 scheduling conference and accusing DexCom of being “intentionally vague” with Abbott and the Court about the current status of the FDA's review. Answering Brief at p. 18. But it is Abbott, not DexCom, that has consistently misrepresented the status of FDA review to this Court. Indeed, Abbott's entire case is based on its incorrect statement, first made to the Court in August 2005, that FDA approval of DexCom's STS device was “imminent.”³

Abbott spends much of its brief speculating as to the motives of DexCom, accusing it of tactical impropriety for asking that the PTO, rather than the Court, first review the validity of the patents in reexamination. The law does not share Abbott's

³ Of course, DexCom hopes, and indeed expects, that this statement—false when made by Abbott in August 2005—will finally become accurate in the Spring of 2006.

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point of view. The law commends DexCom's recourse to the reexamination process early in the litigation, and criticizes Abbott's effort to interfere with the PTO's review through continued litigation. As Abbott well knows, "Congress instituted the reexamination process to shift the burden of reexamination of patent validity from the courts to the PTO." *Canady v. Erbe Elektromedizin GmbH*, 271 F. Supp. 2d 64, 78 (D.D.C. 2002). For this reason, the "[c]ourts have routinely stayed infringement actions pending the outcome of reexamination proceedings." *Softview Computer Prods. Corp. v. Haworth, Inc.*, 56 U.S.P.Q. 2d 1633, 1635 (S.D.N.Y. 2000). This case has only just begun—indeed, DexCom still has not filed an Answer to the Complaint—and the responsible time for DexCom to seek reexamination is now.

Reexamination can be case-dispositive and is not the mere formality suggested by Abbott. The PTO's orders granting reexamination found a "substantial new question of patentability" concerning *all* claims of two of the patents asserted by Abbott, and a decision truly is "imminent" on reexamination of the two other patents. Abbott cannot dispute that there is a 74% likelihood the reexamined claims will be invalidated or modified. Abbott is also notably silent on the "liberal policy in favor of granting motions to stay proceedings pending the outcome of reexamination proceedings." *Guthy-Renker Fitness, LLC v. Icon Health and Fitness Inc.*, 48 U.S.P.Q. 2d 1058, 1060 (C.D. Cal. 1998) (quotation omitted). That policy strongly favors staying a case—like this one—that is in its earliest stages.

Abbott instead invests in knocking down straw men unrelated to the strong policy favoring stays pending reexamination, arguing at length that DexCom's yet-to-be-approved product is inferior to Abbott's yet-to-be-approved product, and that the PTO

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erred in ordering reexamination of the asserted patents. These irrelevant attacks, including Abbott's uninformed criticism of DexCom's correct use of reexamination standards (properly utilizing claim constructions that may be broader than those given by this Court)⁴ cannot change the key, relevant fact: of all reexaminations granted between 1981 and 2004, 74% have resulted in either the cancellation of all claims or at least some change in the scope of the issued claims. Opening Brief at 6. Because that is the likely outcome of the reexamination of Abbott's patents, this case should be stayed to conserve the time and resources of the Court and the parties.

ARGUMENT

A. A Stay Pending Patent Reexamination Is Common At This Early Stage Of Litigation.

Whether a stay should be granted pending patent reexamination is not, as Abbott suggests, a close question for the Court's discretion. "Congress enacted the [USPTO] reexamination procedure to provide an inexpensive, expedient means of determining patent validity which, if available and practical, should be deferred to by the courts."

ASCII Corp. v. STD Entertainment USA, Inc., 844 F. Supp. 1378, 1380 (N.D. Cal. 1994)

(quotation omitted). Accordingly, federal courts almost universally stay matters in favor of patent reexamination when, as here, the case is in its initial stages and no discovery has

⁴ In the context of reexamining patent claims, "the PTO must apply the broadest reasonable meaning to the claim language, taking into account any definitions presented in the specification." *In re Bass*, 314 F.3d 575, 577 (Fed. Cir. 2002) (citing *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984)). "While the claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination." MPEP § 2111.01 (emphasis in original). During examination, which includes reexamination, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989). The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359 (Fed. Cir. 1999).

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occurred. *E.g., Werre v. Battenfeld Techs., Inc.*, No. 03-1471-AA, 2004 U.S. Dist. LEXIS 23250, *3 (D. Or. Nov. 9, 2004); *Tap Pharm. Prods., Inc. v. Atrix Labs., Inc.*, 70 U.S.P.Q. 2d 1319, 1320 (N.D. Ill. 2004); *In re Laughlin Prods., Inc. Patent Litig.*, 265 F. Supp. 2d 525, 532 (E.D. Pa. 2003); *Methode Elecs., Inc. v. Infineon Techs. Corp.*, No. C 99-21142 JW, 2000 U.S. Dist. LEXIS 20689, *6-*7 (N.D. Cal. Aug. 7, 2000); *ASCII Corp.*, 844 F. Supp. at 1381.

DexCom could not find a single case denying a stay when no discovery had occurred and no trial date had been set, and Abbott does not cite such a case.⁵ Abbott relies prominently on cases where courts have denied a motion to stay after much discovery had been conducted and the parties, as well as the courts, had expended substantial time and resources to prepare for trial. For instance, Abbott relies on *NTP, Inc. v. Research in Motion, Ltd.*, 397 F. Supp. 2d 785 (E.D. Va. 2005), for the proposition that the Court may decline to stay this case pending completion of reexamination. But *NTP* involves defendant's request to stay proceedings after a jury verdict and where reexamination was requested nearly two years after the Complaint. Likewise, in another of Abbott's cases (*Soverain Software LLC v. Amazon.com, Inc.*, 356 F. Supp. 2d 660 (E.D. Tex. 2005)), defendant Amazon.com did not move for a stay until after the *Markman* hearing and where discovery was to close in one month. However, where the parties have not engaged in expensive discovery and no trial date has been set, this Court is in accord with the national consensus granting a stay. *See, e.g. Applera Corporation*

⁵ At the time DexCom filed its Motion, no discovery had taken place and no trial date had been set. Several weeks later, one deposition has been taken and the trial date has been set, although it is more than a year and a half away (October 2007).

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v. Thermo Finnigan LLC, No. C.A. 04-1230 GMS (D. Del. Dec. 28, 2005) (staying case pending reexamination where four months remained in discovery and trial date was one year away); *Gioello Enterprises Ltd. v. Mattel, Inc.*, No. C.A. 99-375 GMS, 2001 WL 125340 (D. Del. Jan. 29, 2001) (staying case where some discovery had been taken and parties had filed motions for summary judgment); *accord Guthy Renke Fitness*, 48 U.S.P.Q. 2d at 1060; *Tri-Tech, Inc. v. Tru-Trac Therapy Prods., Inc.*, 31 U.S.P.Q. 2d 1379 (C.D. Cal. 1994) (stay granted after reexamination petition filed early in case) *aff'd*, No. 94-1384, 1995 U.S. App. LEXIS 9788 (Fed. Cir. Apr. 29, 1995); *Calmar, Inc. v. Emson Research, Inc.*, 838 F. Supp. 453, 455 (C.D. Cal. 1993) (same).⁶

The reason for this consensus among the courts when the case is in its early stages is that the “patent reexamination legislation clearly favored the liberal grant of stays by the district courts when patents are submitted for reexamination as a mechanism for settling disputes quickly and less expensively and for providing the district courts with the expertise of the patent office.” *Lentek Int’l, Inc. v. Sharper Image Corp.*, 169 F. Supp. 2d 1360, 1362 (M.D. Fla. 2001) (multiple citations omitted). When a party acts early in patent litigation to seek reexamination by the PTO, the expertise and cost efficiencies for which the reexamination procedure was created can best be effectuated. In this case, reexamination was immediately sought just several months after Abbott first notified DexCom of the four asserted patents in an August 1, 2005 letter. Thus, a stay here is all the more compelling to achieve the purpose of the reexamination process and

⁶ In the handful of cases cited by Abbott where a stay was actually denied, the proceedings were at an advanced stage. See, e.g., *Cognex Corp. v. National Instruments Corp.*, No. 00-442-JJF, 2001 U.S. Dist. LEXIS 25555, *4 (D. Del. June 29, 2001) (discovery closed in three weeks when stay requested); *Xerox Corp. v. 3Com Corp.*, 69 F. Supp. 2d 404, 406-07 (W.D.N.Y. 1999) (reexamination sought after summary judgment briefing).

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Abbott's protestations to the contrary are unconvincing. *See, e.g., Eberle v. Harris*, No. 03-5809 (SRC), 2005 U.S. Dist LEXIS 31885, *5 (D.N.J. Dec. 8, 2005) ("Congress noted its approval of district courts liberally granting stays within their discretion 'to prevent costly pretrial maneuvering which attempts to circumvent the re-examination procedure'" (citation omitted). As of yet, this case has not progressed beyond the initial pleadings stage; the parties have just commenced limited discovery (one deposition), and have not filed any other substantive motions beyond DexCom's motion to dismiss the Complaint. Since the litigation is at such an early stage, Abbott will not be unduly prejudiced by entry of a stay.

B. Abbott Will Not Be "Unduly Prejudiced" By A Stay.

1. Courts Have Not Recognized An Inability To Seek Injunctive Relief As "Undue Prejudice" In Staying Cases Pending Reexamination.

As this Court has previously held, the fact that a stay pending reexamination would prevent Abbott from exploiting its patents while the PTO reconsiders their issuance, does not constitute undue prejudice to Abbott. In *Applera Corporation v. Thermo Finnigan LLC*, this Court stayed the litigation pending PTO reexamination, rejecting Thermo's argument that entry of a stay would constitute "undue prejudice" because it could not enforce its patent:

Thermo asserts that a stay will prejudice it in that it will be unable to enforce its patent. The court is not persuaded. First, Thermo's position assumes the PTO will leave the claims of the '784 patent unaltered after reexamination. Further, while Thermo may suffer some prejudice from a stay, the court is not persuaded that a stay would *unduly* prejudice Thermo, or present a clear tactical disadvantage. On the other hand, granting the stay will simplify the issues and focus the litigation.

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Applera, at p. 4 (emphasis in original). That rationale is even more compelling where, as here, there are four asserted patents with over 270 claims. There is little question that the outcome of the reexamination proceedings will either moot or simplify the issues in this case.

The “liberal policy” in favor of deferring to the PTO’s review can be met only by suspending a patent holder’s ability to wield patents in litigation for a time, and the large majority of courts considering the question have done just that. The impact on the patent holder is mitigated by the statutory mandate that the PTO conduct reexamination proceedings “with special dispatch.” 35 U.S.C. § 305. As such, stays for reexamination are “not for such a protracted or indefinite period as to render its issuance an abuse of discretion.” *Gould v. Control Laser Corp.*, 705 F.2d 1340, 1341 (Fed. Cir.), *cert. denied*, 464 U.S. 935 (1983). Abbott itself concedes the process is unlikely to take more than two years, and acknowledges that “[t]he patents at issue have substantial remaining life.” Answering Brief at 23. Should the patents survive the reexamination process in some form, Abbott will have more than a decade to exploit the patents, seek a permanent injunction and obtain damages.

Given the availability of money damages and other relief, a stay pending reexamination is imposed notwithstanding the potential for market losses to a competitor during its pendency:

[Patentee] claims that a stay would prejudice it because, until the action is resolved, ... plaintiffs can unfairly price their products below [Patentee’s] licensees and thereby gain market share at the expense of [its] licensees. This argument does not, however, establish harm to [Patentee]. If the patent is ultimately found to be valid and infringed, [the accused infringers] will be responsible to [Patentee] for damages -- perhaps treble damages, 35 U.S.C. § 284 -- for

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all the infringing mechanisms that it has sold. Thus, it does not appear that staying the action will result in any financial damage to [Patentee]. In addition, if found to be infringing, [the accused infringers] will be subject to injunctive relief, 35 U.S.C. § 283, which would entirely eradicate their market share with respect to infringing products. Thus, [Patentee's] prejudice argument is unpersuasive.

Softview Computer, 56 U.S.P.Q. 2d. at 1636; *see also Perricone v. Unimed Nutritional Servs.*, No. 3:01CV512(CFD), 2002 U.S. Dist. LEXIS 17613, *9-*10 (D. Conn. July 18, 2002) (similar); *Guthy-Renker Fitness*, 48 U.S.P.Q. 2d at 1061 (similar).

The undue prejudice the courts consider for a stay does not include the inability of a party to exploit the patents subject to reexamination. After all, the PTO has concluded that there is a substantial question of patentability that could lead to the rejection of the asserted patents in their entirety. Since the future of the asserted patents is in substantial doubt, equitable concerns cut against Abbott's desire to exploit these patents before they are invalidated by the PTO, and the Court's interest in judicial economy counsels against the significant expenditure of resources that may be mooted by the PTO's decision. *Tap Pharm.*, 70 U.S.P.Q. 2d at 1320 (even where the patent-in-suit could expire during reexamination, a stay was entered given the "risk of expending substantial resources on trying the validity of patent claims that may ultimately be cancelled or amended by the PTO"); *Hewlett-Packard Co. v. Acuson Corp.*, No. C-93-0808 MHP, 1993 U.S. Dist LEXIS 6449, * 4 (N.D. Cal. May 6, 1993) ("there is clear congressional intent to maximize efficiency and reduce cost in this regard," which is why "district courts often stay patent proceedings pending reexamination").

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2. Abbott's Claim Of Undue Prejudice Is Unfounded And Speculative.

Abbott's entire argument that it will be unduly prejudiced by DexCom getting to market first with its glucose monitoring device is pure speculation. After all, neither party has an FDA-approved device, and neither party has any market share to protect. Given the prematurity of Abbott's case, it is left to fashion its argument from speculation as to how it *might* be harmed in some hypothetical set of circumstances. The theoretical harms imagined by Abbott are not even internally consistent. On the one hand, Abbott states that DexCom will permanently capture a significant share of the short term glucose sensor market. Yet, Abbott also argues that DexCom's product is so inferior that it will irreparably harm the STS market. On the one hand, Abbott argues that short term glucose monitors are revolutionary in their benefit to people with diabetes. Yet, Abbott argues that DexCom's purportedly inferior product could forever "taint" the market. Abbott claims that DexCom's STS is "inaccurate." Yet, DexCom's STS can only launch if it is approved by the FDA, with the necessary finding that the product is both safe and efficacious.

These irreconcilable inconsistencies in Abbott's argument reveal the truth: the purported harm to Abbott from a stay is pure speculation. Indeed, the Court need only look at Abbott's Answering Brief, which is riddled with conditional, speculative words such as "would" (55 times), "if" (16 times), "could" (13 times), "may" or "might" (12 times), and "possible" (6 times). Numerous sentences on nearly every page of Abbott's brief contain one of these telltale signs of speculation.⁷

The crux of Abbott's argument is that a stay would prevent it from seeking an injunction, which will "irreparably damage Abbott's market position" and "hurt Abbott's goodwill and long-term customer relationships." Answering Brief at p. 13. But Abbott

⁷ Abbott also offers speculation that a stay would not serve to simplify this case, arguing that the motion for a stay should be denied because Abbott has other patents that it has not yet asserted, but *may* assert, and its unasserted patents are not covered by the current reexamination requests.

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does not offer a single piece of evidence to support that speculation. The reason: Abbott has no FDA-approved device, no customers and no market share.

Instead, Abbott offers speculation dressed up as a declaration from a purported expert witness, Walter Bratic.⁸ Mr. Bratic is a Certified Public Accountant who makes a living providing expert opinions and testimony on economic damages. Mr. Bratic states that he has "worked on many matters in the pharmaceutical and medical device industries," and then holds himself out as qualified to give expert testimony on the irreparable harm Abbott might someday suffer if DexCom's STS product gains FDA approval and is marketed. Bratic Decl. ¶ 1. One look at Mr. Bratic's CV casts doubt on his expertise in this field. Mr. Bratic has done work in over two dozen other technical fields, including aviation, construction, mining, oil and gas, and telecommunications. *See* Bratic Decl., Ex. 1 at p. 2. Yet, based on his "experience in the pharmaceutical and medical devices [*sic*] industries," he repeats Abbott's argument as his "opinion that Abbott very likely would suffer irreparable harm if DexCom STS were introduced into the diabetes treatment market prior to the introduction of" Abbott's product. Bratic Decl., at ¶ 10.

Mr. Bratic's opinions would perhaps be more plausible if they were supported by evidence, rather than speculation. Mr. Bratic cites to no analysis of the market for continuous glucose sensors. Nor does he cite to any data or analysis of Abbott's expected share of the presently nonexistent, short term continuous glucose monitoring market. Instead, Mr. Bratic merely restates Abbott's argument as his opinion. Mr. Bratic loses any possible credibility by citing statements from Abbott's own Vice President (Mr. Goodnow) "the FreeStyle Navigator is a superior product compared to the DexCom

⁸ Whether by design or innocent omission, Mr. Bratic's declaration contains no oath or affirmation that it has been signed and submitted to this Court under penalty of perjury. *See* 28 U.S.C. § 1746, permitting evidence otherwise requiring a sworn affidavit to be submitted by written declaration when subscribed "as true under penalty of perjury, and dated, in substantially the following form . . . 'I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date).'" The declaration therefore may not be considered and should be stricken in its entirety.

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STS", as a basis for his opinions. Mr. Bratic even offers up expert opinion on future perceptions: "[w]hen Abbott's FreeStyle Navigator product launches it will face a market perception that it has the same limitations as the DexCom STS system, which will tarnish Abbott's...goodwill and reputation." *Id.* at ¶ 12.

Mr. Bratic's adoption of Abbott's argument that DexCom's unapproved, purportedly inferior product carrying a more limited FDA-approved use than Abbott's hoped-for product will harm Abbott is not just speculation—it is offensive speculation. It is based on the inaccurate and offensive premise that diabetes doctors and patients are unsophisticated and cannot discern qualitative differences between products. The opposite is true. Diabetes doctors and patients are exceptionally experienced and sophisticated. *See, e.g.,* www.jdrf.org (website of Juvenile Diabetes Research Foundation International). They are eagerly awaiting improvements in care and will consider each FDA-approved product on its own merits.

C. Deferring To The PTO Will Simplify The Issues And Will Conserve The Resources Of The Court And Parties.

Abbott's Answering Brief contains no consideration of the core reason for staying this case: the Court should not devote its resources to patent cases in which the patents are likely to change, even if they are not completely invalidated. Abbott's stated intent to file a motion for preliminary injunction underscores the importance of a stay to protect DexCom and this Court from wasteful, unnecessary and significant expense.

Even if the stay were denied and Abbott proceeded with a motion for preliminary injunction, it could not succeed, in part *because* of the pending reexamination proceedings. To secure a preliminary injunction, Abbott will carry a heavy burden to show, among other things, that DexCom's invalidity defenses "lack[] substantial merit." *Helifix, Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1351 (Fed. Cir. 2000). Because the PTO

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has already agreed there is a sufficient record to determine that at least one of DexCom's invalidity defenses presents a "substantial new question of patentability" regarding two of the asserted patents (and Abbott admits it is 90% certain the PTO will reach the same result on the other two patents), Abbott simply cannot show there is a substantial lack[] of merit to the defense. *See Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 514 (Fed. Cir. 1990) ("The interpretation in the [PTO's] letter ordering reexamination ... at the very least raises a substantial question [of validity]"); *Whistler Corp. v. Dynascan Corp.*, No. 88 C 8368, 1989 U.S. Dist. LEXIS 1513, *4 (N.D. Ill. Feb. 9, 1989) (denying motion for preliminary injunction because the validity of the asserted patent was at issue in a reexamination proceeding before the PTO). The logical procedure in the context of Abbott's injunctive intentions is to stay the matter, including deferring preliminary injunction proceedings, until after the reexamination process concludes. *See Calmar*, 838 F. Supp. at 455, 457.

In addition, the full array of patent-specific proceedings and analyses will be required in connection with any preliminary injunction motion. Multiple limitations of the 272 asserted claims of the four patents would need to be preliminarily construed by the Court before it could consider Abbott's likelihood of success on the merits. *See, e.g., Jeneric/Pentron, Inc. v. Dillon Co., Inc.*, 205 F.3d 1377, 1380 (Fed. Cir. 2000). For this, the parties would need to provide expert testimony regarding any widely-held understanding of skilled artisans in the technical field at issue. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309 (Fed. Cir. 1999). The Court could find the need for its own independent expert to prepare it for claim construction.

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After construing the terms in the 272 asserted patent claims, the Court would then need to consider the issue of infringement based on that construction, as well as all invalidity defenses. *Jeneric/Pentron*, 205 F.3d at 1380. For this, the parties are likely to deploy at least four additional experts, one for each side on: (1) non-infringement and (2) invalidity. Additional experts could be required for the issue of irreparable harm, as well as potential witnesses regarding the nascent market for continuous glucose monitors, Abbott's claimed irreparable harm, and the effect of an injunction on the public interest. The briefing and declarations are likely to fill banker's boxes.

This extensive amount of work and the gargantuan expense necessitated by Abbott's threatened motion for preliminary injunction would be pursued while the PTO is reviewing whether *all* of the asserted claims of the four patents are invalid. Should the PTO reject or modify the claims, all of this litigation activity Abbott seeks to foist upon the parties and the Court would be a nullity. It is this prospect of gross waste posed by continued litigation that is addressed by a stay. *E.g., Softview Computer*, 56 U.S.P.Q. 2d at 1636 ("It would be a serious waste of both the parties' and the Court's resources if the Markman [claim construction process] and summary judgment proceedings went forward and the claims were subsequently declared invalid or were amended as a result of the reexamination proceeding"); *Guthy-Renker Fitness*, 48 U.S.P.Q. 2d at 1060-61 ("since the Court will need to interpret the pertinent claims of the patent at some point during this case, ... waiting until after the reexamination will provide this Court with the expertise of the PTO").

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D. The PTO Has Elected To Reexamine The Asserted Patents, And Abbott's Attempt To Dismiss The Merits Of The Reexamination Is Irrelevant.

Abbott devotes nearly four pages of its Answering Brief pointlessly second guessing the PTO's decision to reexamine the asserted patents. That argument is irrelevant to this Court's evaluation of the proper factors used to decide a motion for stay pending reexamination. *See Alloc, Inc. v. Unilin Décor N.V.*, No. 03-253-GMS, 2003 U.S. Dist. LEXIS 11917, *4 (D. Del. July 11, 2003) (noting that courts generally consider the following factors: "(1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues in question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set." *quoting Xerox*, 69 F. Supp. 2d at 406).

Consistent with Congress's intent, this Court has correctly deferred to the PTO in previous cases. *See, e.g., Gioello Enterprises*, 2001 WL 125340 at * 2 ("Mattel is entitled by law to request a reexamination. *See* 35 U.S.C. §§ 302-307; 37 C.F.R. § 1.525. The fact that the request was granted means the PTO deems the '434 patent worthy of reexamination."). The Court went on to explain that, "[i]t is not for the court to second guess the PTO's decision to reassess the prior art." Yet that is precisely what Abbott asks the Court to do in pages 8-11 of its Answering Brief. In any event, if Abbott is correct and DexCom's invalidity arguments are so lacking in merit, Abbott will be able to convince the PTO of that fact quickly and the stay will be short-lived.

In making the irrelevant argument that the reexaminations lack merit, Abbott makes the knowingly false assertion that the four asserted patents were "thoroughly examined before issuance", stating that "[t]he Patent Office issued numerous office actions testing and probing the most relevant prior art." Answering Brief at p. 9. A brief review of the prosecution histories of the four asserted patents proves the contrary. Few prior art-based rejections were made, and at least two of the four patents had no such

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rejections.⁹ Nor is it true that the prior art on which DexCom's reexamination requests are primarily based was "tested and probed" by the Patent Office during the prosecution of the asserted patents. Abbott also misleadingly argues that the prior art underlying the reexamination requests was "considered" by the Examiner during prosecution, for example, of the '161 and '478 patents. *See* Answering Brief at p. 10. What Abbott fails to tell the Court is that, with respect to the prosecution of the '161 patent, those references (Sakakida, Wilkins, Johnson, Wilson '407 patent, Sternberg, and Wilson *Clinical Chemistry* article) were marked as "considered" by the Examiner in September 2001 (*See* July 2, 2001 "Communication" from applicants' counsel, attached as Ex. C), several months *after* the PTO had issued a Notice of Allowability of the pending claims in June 2001. (*See* June 4, 2001 "Notice of Allowability," attached as Ex. D). In both the prosecution of the '161 and '478 patents, those key prior art references were disclosed to the PTO in the context of an Information Disclosure Statement that contained hundreds of prior art references. *See, e.g., id.* It is false for Abbott to argue that these key prior art references were "tested and probed" during the prosecution of the asserted patents.

Abbott further misleads by portraying itself as the innovator of implantable continuous glucose monitors. First, Abbott did not innovate anything in this field, but rather purchased TheraSense, Inc. in 2004 to acquire its patents and its technology. Second, TheraSense—whose earliest claimed priority date for any of the four asserted patents is 1993—did not pioneer this field either. As DexCom's reexamination requests

⁹ With respect to the '161 patent, the Examiner issued a single rejection for double-patenting based on the applicants' own prior patents. (*See* December 19, 2000 Office Action, attached as Ex. E). After the applicants submitted a terminal disclaimer, all claims were allowed. (*See* Ex. D, allowing all claims following receipt of March 23, 2001 "Terminal Disclaimer"). No other prior art rejections were made, and the Examiner did not make a single § 112 rejection. With respect to the '478 patent, the Examiner again did not make a single prior art-based rejection, instead making just an indefiniteness rejection (based on improper claim dependency) and a double-patenting rejection issued in error against claims that the applicant voluntarily had canceled by preliminary amendment. (*See* July 22, 1997 Office Action, attached as Ex. F). With respect to the '509 patent, the majority of the claims were determined to be "allowable" in the first office action and a single reference (Ward) was cited against some of the pending claims. (*See* July 24, 2002 Office Action, attached as Ex. G). After the applicant argued that its proposed claims were distinguishable from the Ward reference (*See* November 14, 2002 "Response", attached as Ex. H), the Examiner allowed the claims. (*See* November 25, 2002 "Notice of Allowability," attached as Ex. I).

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forcefully demonstrate, innovation in the field of implantable glucose sensors began in the early 1980's. Indeed, the prior art cited in DexCom's reexamination requests (which DexCom practices) dates back to the work of Motoaki Shichiri and his colleagues in 1985, as well as the early 1990's work of Michiharu Sakakida and George Wilson. These scientists, as well as others, pioneered needle-type implantable devices for continuous glucose monitoring. As the Patent Office has now determined, these prior art references raise "substantial new questions of patentability".

CONCLUSION

Regardless of Abbott's pointless criticism, the Patent Office has now commenced reexamination proceedings. This Court should stay this case to simplify the issues for trial (if any remain following reexamination), conserve the resources of the Court and parties, and avoid inconsistent rulings or advisory opinions. Those considerations far outweigh any potential prejudice claimed by Abbott, particularly given that DexCom sought reexamination at the earliest stages of this litigation.

Josy W. Ingersoll / by G. Hennes (4780)
Josy W. Ingersoll (No. 1088)
Young Conaway Stargatt & Taylor
1000 West Street
Brandywine Building, 17th Floor
Wilmington, DE 19801
Telephone: (302) 571-6689
jingersoll@ycst.com

Attorneys for Defendant
DEXCOM, INC.

Of Counsel:

MORRISON & FOERSTER LLP
David C. Doyle
M. Andrew Woodmansee
3811 Valley Centre Drive, Suite 500
San Diego, CA 92130-2332
(858) 720-5100
Dated: March 21, 2006

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CERTIFICATE OF SERVICE

I, Josy W. Ingersoll, Esquire, hereby certify that on March 21, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

Mary B. Graham, Esquire
Morris Nichols Arsht & Tunnell LLP
1201 North Market Street
PO Box 1347
Wilmington, DE 19899-1347

I further certify that on March 21, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

BY E-MAIL

James F. Hurst, Esquire
Stephanie S. McCallum, Esquire
Winston & Strawn LLP
35 West Wacker Drive
Chicago, IL 60601

YOUNG CONAWAY STARGATT & TAYLOR, LLP

Josy W. Ingersoll / by e-mail (4780)
Josy W. Ingersoll (No. 1088)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
(302) 571-6600
jingersoll@ycst.com

Attorneys for Dexcom, Inc.

CERTIFICATE OF SERVICE

I, John W. Shaw, Esquire, hereby certify that on April 6, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

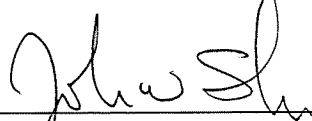
Mary B. Graham, Esquire
Morris Nichols Arsht & Tunnell LLP
1201 North Market Street
PO Box 1347
Wilmington, DE 19899-1347

I further certify that on April 6, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

BY E-MAIL

James F. Hurst, Esquire
Stephanie S. McCallum, Esquire
Winston & Strawn LLP
35 West Wacker Drive
Chicago, IL 60601

YOUNG CONAWAY STARGATT & TAYLOR, LLP



John W. Shaw (No. 3362)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
(302) 571-6600
jshaw@ycst.com

Attorneys for Dexcom, Inc.